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FORM FDA 2359d (11/15) MSRO Form Rev. 6/23/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICESFOOD AND DRUG ADMINISTRATION

MANUFACTURING PLANT INSPECTION REPORT

(Single-Service Containers and/or Closures for Milk and/or Milk Products)

INSPECTING AGENCY/TPC/ CERTIFICATION AGENCY/SSC

Wisconsin Department of Agriculture, Trade and Consumer Protection – Division of Food Safety

NAME AND LOCATION OF PLANT PPC Industires Inc. 10101 78th Avenue Pleasant Prairie, WI 53158 10 LOCKERS AND LUNCHROOMS 1 FLOORS Makeshift devices not used; fasteners, guides, hangers, Smooth; impervious; in good repair... Separate from plant operation; self-closing doors... supports and baffles properly constructed; Joints between walls and floors tight; impervious... Eating/storage of food prohibited in fabrication and (b) good repair. Floor drains properly trapped: sloped to drain... (c) storage areas... (b) Take-off tables and other container contact surfaces 2. WALLS AND CEILINGS Locker and lunchrooms clean...... properly constructed; clean; in good repair... (c) In fabrication areas—smooth; cleanable; light-colored... Cleanable trash containers provided; properly labeled, Grinders, shredders and similar equipment properly In fabrication and storage areas—good repair.... covered.... installed: protected from contamination... (b) (d) Openings in walls and ceilings effectively sealed. Handwashing facilities convenient. (e) Resin storage silos, other containers, constructed to 3. DOORS AND WINDOWS Employee handwashing signs posted. (f) protect resin from contamination; air vents filtered; 11. DISPOSAL OF WASTES All outside openings protected against entrance of air tubes good repair and properly protected.... insects, rodents, dust, and airborne contamination Stored in covered, impervious, leak-proof containers 16.MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES does not apply to production scrap.... Outer doors tight, self-closing.... (b) (a) LIGHTING AND VENTILATION (b) Materials from approved source.... Waste containers properly identified..... (a) Storage of garbage/rubbish meets requirements. Adequate light in all rooms..... Food-grade lubricants used on contact surfaces; stored to 12. PERSONNEL - PRACTICES Ventilation sufficient prevent cross contamination; storage clean and (h) Pressure ventilation systems properly filtered... (c) Hands washed as required.. (a) (b) 5. SEPARATE ROOMS Clean outer garments; hair restraints..... Containers, closures or materials on floor not used..... 17. WAXES, ADHESIVES, SEALANTS, COATING AND INKS abrication areas separate from non-fabrication areas No person affected by disease in communicable form: while when required... a carrier of such disease; or with inadequately protected Handled and stored to prevent cross contamination with Regrinding plastic and paper trim shredding, packaging wounds or lesions shall work in the fabrication areas. (c) non-food-grade materials; storage areas clean and and baling conducted in separate room(s) from Tobacco use in authorized areas only..... ventilated (d) (a) fabrication areas or as Appendix J permits... Unsecured lewelry not permitted in fabrication areas. (e) Jnused materials covered, labeled and properly stored... (b) TOILET FACILITIES-SEWAGE DISPOSAL 13. PROTECTION FROM CONTAMINATION Nontoxic: imparts no flavor or odor: non-contaminating: Disposal of sewage; other waste; in public sewage system Product contact surfaces protected; all materials in complies with 21 CFR Parts 174-178...... (c) or in compliance with Local and State Regulations. process properly protected Fransfer containers clean; covered, properly identified... (d) All plumbing complies with Local and State plumbing Air under pressure directed at materials or product Waxing, when used, performed as required; wax kept at Regulations.. (h) contact surfaces in compliance..... proper temperature 18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT Solid, tight-fitting, self-closing doors..... Air directed at materials or product contact surfaces (c) Handling of container and closure surfaces minimized.... Toilet rooms and fixtures clean: in good repair.... by fans or blowers in compliance.... (d) (c) Adequate light and ventilation; ducts vented to the outside (e) Pesticides approved: EPA registered. Hands sanitized frequently or clean, single-use gloves Proper handwashing facilities... (f) Pesticides used in accordance with directions: worn; sanitizing dispensers convenient... 19. WRAPPING AND SHIPPING Open windows effectively screened... (g) precludes contamination of containers/closures. Employee handwashing signs posted..... Single-service articles in process protected from Single-service articles properly containerized prior to Eating/food storage prohibited. (i) contamination... (f) shipping... (a) Equipment cleaned after use of non-food-grade materials.. 7. WATER SUPPLY Packaged contents protected from contamination... (b) (a) Safe; complies with bacteriological and construction Cross contamination with non-food-grade material Fransportation vehicles clean; in good repair; not requirements (a) (h) used for unapproved uses (c) No direct or indirect connection between safe and No overcrowding of equipment and operations...... Paperboard containers, wrappers and dividers not (i) unsafe water... (b) Toxic chemicals separated from raw materials and (d) reused. Sampled and examined as required.... finished products... Packaging materials in compliance.... (c) (j) (e) Recirculated cooling water used in water baths complies with ood containers manufactured by facility not used for 20. IDENTIFICATION AND RECORDS bacteriological standards, tested semi-annually... storage of miscellaneous items or chemicals... Plant identification on outer wrapping as required. (d) (a) Testing records maintained as required...... 14. STORAGE OF MATERIALS AND FINISHED PRODUCT Glass containers properly labeled. (b) 8. HANDWASHING FACILITIES Away from any wall; soiled outer turns or edges discarded... Required bacteriological tests on file; maintained as Hot and cold and/or warm running water, soap, individual Stored in clean, dry place, protected from splash, insects, required; and in compliance.... (c) towels or air dryers convenient to fabrication areas; Required bacteriological and chemical test records for and dust covered trash containers when required; hand sanitizers Containers and closures stored in original cartons and all component parts used in final assembled product used as Appendix J permits... (a) sealed until used; partially used cartons resealed (d) Handwashing facilities clean... during storage. Information on file from suppliers of raw materials, waxes, (c) 9. PLANT CLEANLINESS Containers for storage of resin, raw and reuse materials adhesives, sealants, coatings and inks indicating Floors, walls, ceilings, overhead beams, fixtures, pipes are covered, clean, impervious and properly identified (d), compliance.. and ducts clean in rooms as required... (a) **X** In-process storage bins that touch the product contact nformation on file from suppliers of packaging materials Plant free of evidence of insects, rodents and birds (b) surface constructed of cleanable, nonabsorbent indicating compliance. Machines and appurtenances clean. (c) **X** material: clean.... 21. SURROUNDINGS 15. FABRICATING EQUIPMENT Surroundings neat and clean and free of breeding areas. Contact surfaces clean: milk plant equipment utilized for conditions attracting or harboring flies, insects or preforming containers clean and sanitized prior to rodents (a) operation.. Driveways graded; no standing water (b) REMARKS (If additional space is required, please place information on the back of this Form or on a separate page.) See attached narrative report. DATE SANITARIAN/SRO/SSC/RMS 4/3/2018 Patrick Zaffino

NOTE: This Form has been developed for use with Appendix J of the Grade "A" Pasteurized Milk Ordinance.

IMS SINGLE-SERVICE SURVEY

PLANT NAME: PLANT #: 55-DATE:

A routine Interstate Milk Shippers (IMS) survey was conducted at this Single Service Manufacturing facility to determine compliance with requirements of the Appendix J of Pasteurized Milk Ordinance (PMO). This survey was conducted by Patrick Zaffino WDATCP Sanitation Rating Officer. Plant personnel accompanying this survey were Michael Xiong and Jeff Christiaansen.

PPC Industries is a SS Plant Type Blown facility with a Partial plant listing for IMS related products. The product produced is used for Primary as well as Secondary packaging.

The following report contains violations noted and documents reviewed during the course of the survey. It is expected that all violations (debited and non-debited) are to be corrected prior to the next routine IMS audit.

A. DEBITED VIOLATIONS:

- 9a) Plant Cleanliness: The area surrounding the water chiller is in need of cleaning and dusting.
- 9c) The bag roller used for packaging the roll, needs to be cleaned and painted. Flaking paint on the top where tertiary packaging was kept.

B. NON-DEBITED VIOLATIONS: None

<u>C. NOTES:</u> The water drain line for condensate from the air compression unit, was submerged into the floor drain. The line was dirty and drains are common areas for listeria. The line does not cross connect with potable water, but submerged lines in plants should be air gapped to prevent contamination of equipment or areas.

D. REQUIRED DOCUMENTATION:

The following documentation is required. It is recommended that documentation supporting these items be maintained in an IMS binder to facilitate future IMS audits.

- 01. Line sanitization procedure prior to running IMS product.
- 02. Photos of resin silo air intake filters.
- 03. Pest control records.
- 04. Annual RPZ back-flow preventer tests.
- 05. Approval letters for resin, colorants, and inks.
- 06. Documentation that wraps and liners comply with applicable sections of 21 CFR, Sections 174-178 and the bacteriological standards of the PMO, Appendix J, Section C.

E. CONCLUSION:

It is important that <u>all</u> documentation is available and all violations are corrected prior to the next routine IMS audit. Based upon a passing score of 97 it will be recommended that this facility be included on the IMS List as a certified supplier of single service product. This report was discussed with

contact me at Patrick.zaffino@wisconsin.gov or	r 608-712-9637.	

management at the conclusion of the survey. Should you have questions or concerns, feel free to

U.S. Department of Health and Human Services
Food and Drug Administration

STATUS OF MANUFACTURING PLANTS

(SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant PPC Industires Inc.		
Number 55-4840		
Date of Certification 4/3/2018	Sanitation Compliance Rating ¹	97

		ITEMS OF SANITATION																												
NAME OF PLANT		Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From	Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of	Containers and/or Closures	Waxes, Adhesives, Sealants,	Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping		idenuncation and Records	Surroundings	Bacterial Count*	Coliform Count*	Total Debits²	REMARKS
	ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13	13 d,e,h,j	14	15	16 a	16 b,c	17	17 c	18	19	20 a,b,f	20 c,d,e	21				
	WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10		
PPC Industires Inc.										3																			3	
TOTALS										3																			3	

Footnotes:

¹Sanitation Compliance Rating = 100 – Total Debits

²Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)

*Used only when not in compliance.

FORM FDA 2359e (11/15)